Patient Safety Alert

Veterans Health Administration Warning System
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Item: **Product Recall:** Watson Pharmaceutical Propafenone HCL tablet Lot # 112680A, with expiration date of July 31, 2010.

Specific Incident: Watson Pharmaceutical, Inc. is recalling one specific lot number (112680A) of Propafenone HCL 225 mg tablets, shipped between October 15, 2008, and November 26, 2008, because some tablets may contain slightly higher levels of the active ingredient than specified. This could cause patients to receive more medication than prescribed to treat cardiac arrhythmias, with the potential for serious side effects including worsening or new arrhythmias or hypotension. (See ATTACHMENT 1)

Actions: 1. By Close of Business April 13, 2009, Pharmacy Chiefs shall:

A. Determine whether the affected lot number (refer to lot number provided above) was dispensed to any patient(s). The attached VAMC data (ATTACHMENT 3) may be used as a guide (data may not include direct purchases/drop shipments and is not lot specific). It has been determined that the lot number provided above was not dispensed from CMOP.

B. If an affected lot number was dispensed to patients, then:

- Identify the patient(s).
- Contact patient(s) who may have received the affected product by any appropriate method.
  - A sample letter can be found at: http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc. (See ATTACHMENT 2)
  - This template can be altered according to site-specific needs.
- Provide patient(s) with instructions on the following:
  - How to obtain a new supply of medication.
  - How to return the medication being recalled to the pharmacy.
  - To continue taking the medication with the affected lot number until they receive a new supply of propafenone. When correct medication

is received, patient should begin taking the new medication and return the recalled supply as instructed.

- Include a warning that states:

*"Symptoms of too much propafenone may include an irregular heartbeat, a slow heartbeat, extreme drowsiness, or feeling light headed. Patient(s), family members, or caretakers should call the patient's Healthcare Provider and/or seek care **immediately** if the patient who is receiving propafenone feels that their heart is beating faster, or is irregular more often or for a longer period of time, or who have become light headed, or are having problems with breathing."*

C. Report any adverse reactions experienced with the use of this medication to the VA ADERS program.

2. By Close of Business April 14, 2009, the Facility Chief of Staff shall ensure that individuals designated to contact patients complete Action 1B above and document as delineated in VHA Directive 2008-078 "National PBM Drug Safety Alert Distribution".

3. By Close of Business April 15, 2009, the Patient Safety Manager shall assure that this Alert has been addressed and the action status updated on the VA's Hazardous Recalls/Alerts website: http://vaww.nbc.med.va.gov/visn/recalls/index.cfm.

Source: Manufacturer and FDA

Attachment: 1. FDA MedWatch safety summary.

2. Sample letter to patients.

3. VAMC data.

Contact: Keith Trettin at the VA National Center for Patient Safety (734) 930-5890 and/or Vincent Calabrese at PBM (708) 786-7862.

ATTACHMENT 1. FDA MedWatch Safety Summary

The FDA Safety Information and Adverse Event Reporting Program

FDA and Watson Pharmaceuticals notified healthcare professionals and patients of a recall of Propafenone HCL 225 mg tablets, a drug product used to treat cardiac arrhythmias. The drug is being recalled because some tablets may contain slightly higher levels of the active ingredient than specified. Because it has a narrow therapeutic index, some patients who are particularly sensitive to small variations in dose may experience potentially serious side effects, including arrhythmias (irregular heartbeat) or low blood pressure. The affected lot [lot number 112680A, expiration date July 31, 2010] of Propafenone HCL tablets was shipped to customers between October 15, 2008 and November 26, 2008. The Press Release includes instructions for identifying and returning the affected product.

Read the MedWatch safety summary, including a link to the company Press Release, at:

http://www.fda.gov/medwatch/safety/2009/safety09.htm#Propafenone

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You are encouraged to report all serious adverse events and product quality problems to FDA MedWatch at www.fda.gov/medwatch/report.htm

Update your subscriptions, modify your e-mail address, or stop subscriptions at any time on your Subscriber Preferences Page. You will need to use your e-mail address to log in. If you have questions or problems with the subscription service, please contact support@govdelivery.com.

This service is provided to you at no charge by U.S. Food & Drug Administration (FDA).

ATTACHMENT 2. Sample letter to patients

Department of Veterans Affairs
Veterans Health Administration

<INSERT DATE HERE>

Dear Veteran:

You are receiving this letter because your prescription for <**INSERT DRUG NAME HERE**> is being recalled for <**INSERT REASON FOR RECALL HERE**>. <**INSERT DRUG NAME HERE**> is a medication used for <**INSERT INDICATION HERE**>.

☐ We were unable to contact you by phone on_____.

☐ Please return ALL of your OLD supply of <**INSERT DRUG NAME HERE**> to _____.

☐ Enclosed is a NEW supply of <**INSERT DRUG NAME HERE**>. Please begin taking medication from your NEW supply with your next dose and stop taking any old supply of this medication.

☐ Please contact your provider or pharmacy at < **INSERT PHONE NUMBER HERE**> for further instructions.

Call your Healthcare Provider and/or seek care immediately if you feel that you are experiencing <INSERT SYMPTOMS HERE>.

Contact your VA Pharmacy <**INSERT CONTACT INFORMATION HERE**> if you have any questions about this letter or your medications.

Sincerely,

ATTACHMENT 3. VAMC data

Selected Date Range: 09/01/2008 to 03/24/2009

Actual Date Range: 10/15/2008 to 03/23/2009

Cust#	Customer Name	Address	City	St	Zip Code	EMost#	NDC/UPC	Item Description	Orig Invc	Invc/Cred #	Invoice Date	C	Ordr	Fill	Ret	Net	UOM
283629	VA MEDICAL CENTER OUTPAT	HIGHWAY 6 WEST	IOWA CITY	IA	52246	1298835	591058301	PROPAFENONE TAB 225MG WAT 100@	7375084386	7375084386	2/25/2009	N	3	3	0	3	EA
283629	VA MEDICAL CENTER OUTPAT	HIGHWAY 6 WEST	IOWA CITY	IA	52246	1298835	591058301	PROPAFENONE TAB 225MG WAT 100@	7375424716	7375424716	2/27/2009	N	1	1	0	1	EA
283629	VA MEDICAL CENTER OUTPAT	HIGHWAY 6 WEST	IOWA CITY	IA	52246	1298835	591058301	PROPAFENONE TAB 225MG WAT 100@	7375589732	7375589732	3/2/2009	N	2	2	0	2	EA
283629	VA MEDICAL CENTER OUTPAT	HIGHWAY 6 WEST	IOWA CITY	IA	52246	1298835	591058301	PROPAFENONE TAB 225MG WAT 100@	7377160812	7377160812		N	3	3	0	3	EA
488093	VA MEDICAL CENTER-603	800 ZORN AVENUE	LOUISVILLE	KY	40206	1298835	591058301	PROPAFENONE TAB 225MG WAT 100@	7374358647	7374358647	2/19/2009	N	3	3	0	3	EA
488093	VA MEDICAL CENTER-603	800 ZORN AVENUE	LOUISVILLE	KY	40206	1298835	591058301	PROPAFENONE TAB 225MG WAT 100@	7378165437	7378165437	3/23/2009	N	1	1	0	1	EA
953231	VA OUTPATIENT CLINIC	9912 LITTLE ROAD	NEW PORT RICHEY	FL	34654	1298835	591058301	PROPAFENONE TAB 225MG WAT 100@	7376731728	7376731728	3/10/2009	N	3	3	0	3	EA